



MethodSense News  
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*MethodSense develops practical and sustainable solutions for your life science company that deliver strategic value.*

### 3 Tips for Managing Your Life Science Software

#### Your Software is in the Regulatory Spotlight:

CDRH posted in March the first in a series of podcasts designed to educate the industry about Medical Device Software titled [CDRH Regulated Software: An Introduction](#). In this first installment, FDA medical device software compliance expert John Murray explains in general terms the software regulatory interests of CDRH and the applicability of 21 CFR Part 820 for the management and maintenance of software falling under CDRH oversight.

In July, [CDER announced](#) that it would be conducting inspections focused on 21 CFR Part 11 and that “[t]he Agency intends to take appropriate action to enforce Part 11 requirements for issues raised during the inspections that do not fall under the enforcement discretion discussed in the Guidance.”

A few months ago, IEC 62304 came into force as a harmonized EU standard regulating the software development processes for medical device manufacturers. IEC 62304 satisfies the Medical Device Directive requirements and is accepted by the FDA as evidence that medical device software has been developed to an acceptable standard.

Software in the life science industry has not been this close to the regulatory center stage since 2003. Now is the time to revisit your life science company’s management of software to assess and remediate potential risks.

#### 3 Tips for Assessing and Reducing Life Science Software Risks:

**Tip #1: Review-** For many companies the priority of day-to-day management of software has slipped and has become stale in recent years. Whether your company uses software to manage critical functions subject to regulatory oversight (e.g. clinical trials, adverse event reporting, or regulated product inventory) or software is a component of your regulated product (e.g. medical device or diagnostic), your company should review within an appropriate regulatory framework the condition, relevance and currency of documentation, policies, and processes around software. Some questions to ask in this process might include “Has the software been upgraded or technology changed since the last revision of the documentation?”, “Have we lost personnel whose expertise and knowledge over the years were important for the management, implementation, training, configuration or development of the software?”, and “Have we historically adopted tactically convenient methods in either our validation, training or development efforts that might not stand up to the emerging regulatory climate?”.

**Tip #2: Renewal-** Your review process should result in a gap analysis and a risk based remediation plan. But it cannot be just any remediation plan. Every life science business has nuances of its own. Products, resources, internal skills, corporate and marketing strategies, applicable regulations and position in the commercialization food chain are some factors that create a unique identity for each life science company. How you revitalize your software documentation and management practices should blend your business, IT, regulatory and quality management expertise into your plan. In short, make your implementation regulatively germane but pragmatically sustainable for your business.

**Tip #3: Refocus-** Your critical systems and technologies, either for operationalizing your business (as in the case of software applications) or as a core asset of your company (as in the case of commercialized products that include software or is software), tends to monopolize employee attention. Changes in how a company interacts with software likewise tend to monopolize employee attention. Whether change positively or negatively affects employee focus will determine the successful implementation of your remediation plan. Your success drivers will

include communications that effectively teach how regulatory compliance contributes to corporate long term success and how the chosen pragmatic approach lessens challenges introduced by change. Most critically, strong executive leadership and support will result in the right attitudes and results.

### **Case Study: Life Science Company Seeks Compliance with New Operations Software**

**Background:** A medium sized life science company recognized that a critical internal enterprise application was aging and becoming technologically obsolete. The company sought to upgrade the solution with the adoption of a Software-as-a-Service (SaaS) application. After a review of the current state of their Quality Management System, they concluded that the QMS inadequately managed vendor selection, validation and on-going management of a SaaS solution.

**Solution:** MethodSense developed a plan to “right-size” the company’s QMS by blending into a roadmap the company’s business goals and resources, practical strategies for technology validation and maintaining technologies in a validated state with a focus that included SaaS solutions. The regulatory framework for the roadmap consisted of FDA Guidelines and industry standards including Process Validation and Guide for Validation of Automated Systems (GAMP). Significant components of the QMS were renewed giving the SOPs greater day-to-day relevance to the operations of the company and making them significantly easier to use.

**Return:** Significant improvement in compliance and auditability. The new SaaS solution went through an efficient validation cycle. The streamlined, easier to use QMS was welcomed by employees making compliance easier which subsequently resulted in the generation of appropriate records and transparent, auditable evidence of best practices.

### **About MethodSense**

MethodSense is a Life Science service company adding value to pharmaceutical, medical device and contract service companies with the convergence of Quality, Regulatory and Technology Expertise. Where technology impacts your company, either as a critical business solution or part of your product portfolio, MethodSense can contribute to your success. MethodSense delivers FDA compliance strategies, quality system development, process and validation strategies and execution, vendor and internal audits, software development methodology optimization, software design control evaluations, risk remediation and GxP, 21 CFR Part 11, ISO, HIPAA, CMM expertise. We invite a discussion and your communication today.